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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,975	04/26/2007	David A. Cook	334498008US01	5929

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EXAMINER	
ANDERSON, JERRY W	
ART UNIT	PAPER NUMBER
1781	
MAIL DATE	DELIVERY MODE
03/15/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,975	COOK ET AL.	
	Examiner	Art Unit	
	JERRY W. ANDERSON	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/07/06; 2/13/08; 11/18/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I, claims 1-24 in the reply filed on 03/01/11 is acknowledged

2. Claims 25-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/01/11

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims1 and 13, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "soy meal " in claims 1 and 13 is used by the claims to mean the soy component of the feed composition. The term is indefinite because the specification

does not clearly redefine the term. The applicant defines soy meal to comprise a mixture of whole soybean meal and soy germ meal, (¶ 12, specification) however, in the same paragraph, the applicant states that one or both of the soy germ meal or the soybean meal may be a defatted soy meal. (¶ 12, specification)

6. The term "soy meal" is not clearly defined, it can not be both a combination of whole soybean meal and soy germ meal and either soy germ meal or soybean meal. The metes and bounds of the claim are not known, thus the claim is indefinite.

7. Claims 2-12, and 14-24, being dependent upon claims 1 and 13, respectively, are, likewise, rejected under 35 USC 112 2nd.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 1, 5, and 6, are rejected under 35 U.S.C. 102(b) as being anticipated by Burroughs, W. (2,751,303)**

10. **Regarding claims 1, 5, and 6,** Burroughs discloses animal (cattle, lambs) feed comprising 50 parts clover hay, 38 parts corn, 10 parts molasses, and two parts minerals with urea, and approximately 0.2 g genistin per pound feed. (440 ppm) (col. 9, line 59-col 10, line-36, '303)

11. Other feed compositions used were 56 parts corn, 40 parts hay, and 4 parts soybean meal. (col. 8, lines 33-39, '303) and genistin equivalent to 1 microgram of stilbesterol per pound feed. (col. 8, lines 35-39, '303)

12. **Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Payne, R. L., Dietary effects of soy isoflavones on growth and carcass traits of commercial broilers, Poul. Sci. 80 (2001) 1201-2107**

13. **Regarding claims 1and 6,** Payne discloses an animal feed comprising about 20 % soybean meal, wherein the feed composition contains 207 and 346 ppm isoflavone, (table 1, pg 1203, Payne) and the isoflavones are daidzein, genistein and glycitein. (pg 1201, col. b, ¶ 1, Payne)

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. **Claims, 1-6, 11-18, and 23-24, are rejected under 35 U.S.C. 103(a) as being unpatentable over Jhanjan, S., et al., (EP 0 925 723) in view of Kim, B-H., et al. (5,952,230)**

17. **Regarding claims 1, 2, 3, 4, 5, 13, 14, 15, 16, and 17**, Jhanjan discloses the claimed invention, including a feed composition comprising 5 % soybean meal, and the remainder fishmeal, cereals, fat. (table 3A, pg 10, '723) wherein the soy product contains isoflavones varying from 0 to 934 ppm. (table 1, pg 7-8, '723)

18. However, Jhanjan lacks the use of a soy product with enhanced levels of isoflavones.

19. Kim discloses a soy embryo separation method that produces soybean embryo meal that is 95 % embryo and contains approximately 2 % isoflavones, (col 1, lines 28-33, col. 3, lines 15-17, '230)

20. It would have been obvious to one of ordinary skill in the art that the embryo of the soybean of Kim is also known as the germ of the soybean.

21. The embryo soymeal of Kim, containing about 2 % isoflavones, about 20,000 ppm, when added in the 5 % level of Jhanjan would yield a feed composition with about 1000 ppm.

22. Jhanjan and Kim are both engaged the development of soy bean products for use as comestibles for human consumption or as feed stocks for animals for human consumption.

23. It would have been obvious to one of ordinary skill in the art to incorporate the soy embryo meal of Kim in the feeding studies of Jhanjan considering that Jhanjan was

looking at the effect of different sources of proteins, and various levels of isoflavones on weight gain of piglets. (Table 1 pg 8, ¶ 69, 723) Jhanjan states that isoflavones are beneficial, (¶ 32, 41,'723) and used a feed composition with isoflavones levels varying from 93-200 ppm. (¶ 69, 723) Jhanjan also stated that a preferred product contained an isoflavone content that exceeds the normal level of 900 ppm. (¶ 37, 723) The embryo soymeal of Kim would have extended the experimental range, and further the incorporation of said embryo soymeal could be performed with a reasonable expectation of success.

24. **Regarding claims 6 and 18,** Jhanjan and Kim disclose the claimed invention, as discussed above, including that isoflavones, included genistein, (col. 1, line 27, 29-32, '230, ¶ 41, 723) and daidzein. (¶ 41, 723)

25. It would have been obvious to one of ordinary skill in the art that the common isoflavones of soy are genistein, daidzein, and glycitein, and although Kim and Jhanjan are silent as to the presence of specific isoflavones, that said isoflavones are naturally occurring in the soy meal, and absent some specific procedure for the removal of a specific isoflavone, all of the aforesaid isoflavones would be present in the final concentrate.

26. **Regarding claims 11, 12, 23, and 24**, Jhanjan, and Kim disclose the claimed invention, as discussed above, including the isoflavones are a natural component of the soy, and not an extract. The applicant has defined a natural component isoflavone as one that has not been chemically extracted from the soybean. (line 30-35, pg 5,

specification) The embryo soy meal of Kim was mechanically separated from the soybean by crushing and sifting. (col. 2, line 65- col. 3, line 18, '230)

27. **Claims, 7-10 and 19-22, are rejected under 35 U.S.C. 103(a) as being unpatentable over Jhanjan, S., et al., (EP 0 925 723) in view of Kim, B-H., et al., (5,952,230) and further in view of Beaver, M.J. (WO 02/37987)**

28. **Regarding claims 7, 8, 9, 10, 19, 20, 21, and 22**, Jhanjan, and Kim disclose the claimed invention, as discussed above, including a feed composition comprising 5 % soybean meal, and the remainder fishmeal, cereals, fat. (table 3A, pg 10, '723) wherein the soy product contains isoflavones varying from 0 to 934 ppm. (table 1, pg 7-8, '723) and a soy embryo separation method that produces soybean embryo meal that is 95 % embryo and contains approximately 2 % isoflavones. (col. 1, lines 28-33, col. 3, lines 15-17, '230) The embryo soy meal of Kim, containing about 2 % isoflavones, about 20,000 ppm, when added in the 5 % level of Jhanjan would yield a feed composition with about 1000 ppm.

29. Jhanjan and Kim lack a soy meal that contains a mixture of the embryo soy meal and whole soybean meal.

30. Beaver discloses a soy germ concentrate containing soy germ, residual hulls, and small meat pieces and the concentration of the soy germ is generally 30-70%. (lines 21-24, pg 9, '897) The isoflavone content of the substantially pure soy germ is approximately 2.5%. (lines 25-26, pg 17, '987) Levels of isoflavone in soy meal are reduced by about 5-20 %. (line 5-6, pg 18, '987)

31. The product of Kim and Beaver are essentially identical, both being produced by a mechanical crushing and separation process, the main difference being the purity of the final product, Kim about 95 % (col. 3, lines 16-18, '230) and Beaver 30-70 %. (lines 21-24, pg 9, '897)

32. It would have been obvious to one of ordinary skill in the art, that, the process of Beaver, which was capable of being easily introduced into an industrial process. (lines 11-13, pg 3, '987) would produce the soy germ concentrate with the desired isoflavone concentration at greater convenience and cheaper cost, than the Kim procedure. Therefore, the use of the Beaver product would have economical advantages, and it would have been obvious to one of ordinary skill in the art to use said product in the Jhanjan and Kim procedure, and that said substitution could be performed with a reasonable expectation of success.

33. As to the use of whole soybean meal and a soy germ concentrate, Beaver states that the soy germ constitutes approximately 30-70 % of the soy germ concentrate, and since the source of the soy germ concentrate is whole soy bean, logically, the remainder, 30-70%, residual hulls and small meat pieces, is derived from whole soy beans, and thus it would have been obvious to one of ordinary skill in the art to be the same as whole soy bean meal.

Conclusion

See MPEP § 714.02 which states: "The prompt development of a clear issue requires that the replies of the applicant meet the objections to and rejections of the

claims. Applicant should also specifically point out the support for any amendments made to the disclosure." Support for amendments includes any new or amended claims

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY W. ANDERSON whose telephone number is (571)270-3734. The examiner can normally be reached on 7 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. W. A./
Examiner, Art Unit 1781

/C. SAYALA/
Primary Examiner, Art Unit 1781